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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
CONLEY, SEAN E

ART UNIT	PAPER NUMBER
1744	15

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/580,822	KIS ET AL.	
	Examiner	Art Unit	
	Sean E Conley	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed January 2, 2003 has been considered for examination. Claims 15-20 have been canceled by the amendment and new claims 21-29 have been added and are now pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0322134 in view of GB 1,544,260.

EP 0322134 discloses a method of packaging and steam sterilizing a pharmaceutical product such as saline solution. A semi-rigid squeezable polypropylene bottle is filled with a pharmaceutical product and once the bottles are sealed and prepared for sterilization they are inserted into an autoclave. The individual bottles are filled to the maximum internal volume with the pharmaceutical product thus eliminating any air present. The elimination of the air inside the bottle prevents the formation of dimples in the polypropylene during the sterilization. The autoclave serves the purpose of sterilizing the bottles using an application of steam at temperatures of 121 °C (see column 3, line 29 –column 6, line 12 and figures 1 and 2). EP 0322134 further teaches that the lids or caps of the bottles can be formed of other polymeric materials other than polypropylene (see column 3, lines 29-49). Another well-known material used to make pharmaceutical packages is polyethylene and furthermore, high-density polyethylene is known to have a high heat resistance and withstands heat sterilization. Therefore, the use of other materials such as high-density polyethylene would result in a modulus of elasticity that is different than polypropylene.

GB 1,544,260 discloses a method for sterilizing a flexible pharmaceutical package. The flexible package is filled with a pharmaceutical product prior to the sterilization and the internal volume of each flexible container exceeds the volume occupied by the liquid contents under the conditions of temperature and pressure within an autoclave during sterilization. Once the package has been filled it is placed in a sterilizing autoclave chamber **38** and the pressure and temperature are adjusted as a function of time. A counterpressure is used to prevent any deformation that would result from the presence of air inside the bottle. The elevated external pressure (counterpressure) for the sterilization process should be at least sufficient to balance the internal pressure induced in the flexible container by the presence of air and at most insufficient to distort the container. The pressure and temperature adjustments depend on the size and materials of the container to be sterilized. These pressure and temperature adjustments are controlled electronically by a control system **54**. (see page 1, lines 64-96 and page 2, lines 1-13 & 97-112). The regulating of the pressure and temperature by the control system prevents deformation of package being sterilized. The specific package material disclosed in the reference is a nylon-polypropylene-polyethylene copolymer laminated sheet that is formed into a tube.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of EP 0322134 and replace the means of preventing deformation (the step of completely filling the bottle with liquid and the substantial elimination of air which prevents dimples in the bottle) with the means to prevent deformation taught by GB 1544260 (the step of filling the bottles with liquid

wherein the internal volume of the bottle exceeds the volume of the liquid thus having air present in the bottle, and then regulating the pressure inside the autoclave to prevent deformation) in order to sterilize the bottles using an alternate but equally effective method.

Regarding the wall thickness of the package, it is a well-known standard to one of ordinary skill in the art that pharmaceutical packages made of polypropylene have a wall thickness in the range of 0.3 mm to 0.6 mm.

Applicant's Arguments

6. The applicant recites that the "cited references provide no reasonable expectation of success that one could autoclave a partially full polypropylene container, and in fact predict failure." Also, the applicant argues that one cannot disregard the teachings of EP 0322134 with regards to the effect of air in a polypropylene bottle while autoclaving.

Response to Arguments

7. The applicant's arguments have been considered but are not persuasive. The examiner agrees that EP 0322134 does teach that if you leave air in a polypropylene bottle during the step of autoclaving you will get dimples. However, the reference to GB 1544260 has an additional method step not disclosed by EP 0322134, which is using a counterpressure inside the autoclave to match the pressure from the air inside the flexible package. The counterpressure prevents any deformation that would result

from the presence of air inside the bottle. Therefore, GB 1544260 solves the problem disclosed by EP 0322134 of autoclaving flexible packages that contain both a fluid and air inside the package.

Furthermore, both of the references are directed to solving the same problem. The problem is sterilizing a flexible, squeezable pharmaceutical package inside an autoclave without deforming the packages. The package in the method of GB 1544260 is made of a flexible nylon-polypropylene-polyethylene copolymer material and therefore, it would have been obvious to one of ordinary level of skill in the art to modify the method of EP 0322134 based on the teachings in the method of GB 1544260 in order to treat other flexible pharmaceutical packages such as polypropylene bottles and tubes comprising laminated polypropylene foil.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (703) 305-2430. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310.

When filing a FAX in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite the processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

SEC

March 19, 2003

Robert J. Warden, Sr.

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SUPERVISORY PATENT EXAMINER
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